In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-531V
Filed: November 6, 2024

TARA ELVIRA, on behalf of D.E.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner.
Adam Nemeth Muffett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On April 14, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that her minor child suffered atypical Kawasaki disease caused-in-fact or significantly aggravated by his February 26, 2015 pneumococcal conjugate vaccination. (ECF No. 1.) For the reasons set forth below, petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations,

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

including showing that an individual received a vaccination covered by the statute; received it in the United States; has received no previous award or settlement on account of the injury; and has suffered a serious or long-standing injury. In particular, in order to demonstrate a compensable injury under the Vaccine Act, a vaccinee must have either:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 300aa-11(c)(1)(D) (referred to herein as the statutory "severity requirement").

The petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ultimately,

petitioner must satisfy what has come to be known as the *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.[3] *Id*.

A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. § 300aa-13(b)(1). A petitioner may also rely upon circumstantial evidence. *Althen*, 418 F.3d at 1280. The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. While scientific certainty is not required, that expert's opinion must be based on "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case, including having the discretion to decide cases without an evidentiary hearing. Vaccine Rule 3(b)(2); Vaccine Rule 8(a); Vaccine Rule (d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the

[3] Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a preexisting injury, as petitioner has pleaded in the alternative, the petitioner must establish the three *Althen* prongs along with three additional factors described in the prior *Loving* case. *See Loving ex rel. Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Loving,* 86 Fed. Cl. at 144.

petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993).

In this case, petitioner has alleged that the pneumococcal vaccine caused atypical Kawasaki disease, which is not listed on the Vaccine Injury Table. Therefore, petitioner must satisfy the above-described *Althen* test for establishing causation-in-fact. However, this case also presents a threshold issue with respect to the above-discussed severity requirement.

II. Procedural History

This case was originally assigned to Special Master Millman. (ECF No. 4.) Petitioner initially filed medical records marked as Exhibits 1-5 and upon review of those records, Special Master Millman issued an Order to Show Cause why this case should not be dismissed. (ECF Nos. 6, 8.) The initial petition had alleged that D.E.'s injury satisfied the statutory severity requirement because D.E. underwent a lumber puncture during his hospitalization, which petitioner asserted constituted a "surgical intervention." (ECF No. 1, p. 4.) However, in her Order to Show Cause, Special Master Millman rejected that premise. (ECF No. 8.)

In a follow up status conference, petitioner requested an opportunity to instead demonstrate that D.E. had suffered residual effects of his injury for at least six months on the basis that he was barred from receiving live-virus vaccines for a period of months. (ECF No. 9.) Specifically, petitioner argued that a restriction from live virus vaccines was due to D.E.'s immune system remaining in a weakened state as a result of his IVIG treatment. (ECF No. 24, pp. 1-2.) Petitioner amended her petition accordingly (ECF No. 12) and the parties completed various filings on that point (ECF Nos. 13, 15-17, 20, 22; Exs. A, 6-9),[4] which was disputed. On January 12, 2018, Special Master Millman issued an order finding that D.E.'s lumbar puncture did not constitute a surgery for purposes of the severity requirement but that she "finds that petitioner's argument that D.E. experienced more than six months of sequalae is sufficient to satisfy at this juncture the statutory requirement that D.E.'s alleged vaccine

[4] Petitioner filed three pieces of medical literature. (Jane C. Burns & Allessandra Franco, *The Immunomodulatory Effects of Intravenous Immunoglobulin Therapy in Kawasaki Disease*, 11 EXPERT REV. CLINICAL IMMUNOLOGY 819 (2015) (Ex. 7); *Kawasaki Disease: Complications, Treatment and Prevention*, AM. HEART ASS'N (May 8, 2017) (Ex. 8); Jane W. Newburger et al., *Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Statement for Health Professionals from the Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease, Counsel on Cardiovascular Disease in the Young, American Heart Association*, 114 PEDIATRICS 1708 (2004) (Ex. 9).) Respondent filed a report, with supporting literature, by Dr. Stacy B. Strayer. (Ex. A; Jordan S. Orange, *Immune Globulin Therapy in Primary Immunodeficiency*, UPTODATE (Sept. 26, 2017) (Ex. A, Tab 1); Arthur J. Silvergleid & Mark Ballow, *Overview of Intravenous Immune Globulin (IVIG) Therapy*, UPTODATE (Feb. 23, 2016) (Ex. A, Tab 2); Jan E. Drutz, *Measles, Mumps, and Rubella Immunization in Infants, Children, and Adolescents*, UPTODATE (Oct. 31, 2017) (Ex. A, Tab 3); Robert Sundel, *Kawasaki Disease: Initial Treatment and Prognosis*, UPTODATE (Mar. 29, 2017) (Ex. A, Tab 4)).

injury lasted more than six months." (ECF No. 24, pp.1- 2.) As discussed further in the analysis below, Special Master Millman accepted petitioner's argument based on the fact of the restriction from receiving a live virus vaccine without resolving the competing evidence presented by the parties with respect to whether D.E. actually did have a weakened immune state.

Over the course of the following year, the parties exchanged expert reports. (ECF Nos. 30-31, 33-36.) Petitioner filed the opinion of rheumatologist/immunologist M. Eric Gershwin, M.D. (Exs. 10-23.) Respondent filed opinions by immunologist Andrew MacGinnitie, M.D., Ph.D., and cardiologist Scott Yeager, M.D. (Exs. B-D.) Respondent filed his Rule 4 Report recommending against compensation in February of 2019. (ECF No. 37.) Respondent asserted that his experts should be viewed as more persuasive and further that Dr. Gershwin's opinion was inadequate to meet the three-part *Althen* test. (*Id*. at 8-11.) Respondent also continued to dispute that petitioner's claim satisfied the statutory severity requirement. (*Id*. at n. 6.)

Thereafter, this case was reassigned to the undersigned in June of 2019 upon Special Master Millman's retirement. (ECF Nos. 41-42.) After the case was reassigned, a Rule 5 status conference was held to guide the parties' litigation of the case. (ECF No. 45.) Neither D.E.'s diagnosis of Kawasaki disease nor its onset appeared to be disputed. (*Id*. at 1.) However, petitioner was advised that the issue of whether petitioner's claim satisfied the statutory severity requirement remained to be definitively resolved.[5] (*Id*. at 2.) Preliminary views with respect to *Althen* prongs one and two were also provided and it was noted that, based on the issues being presented by the parties, further focus should likely be on the opinions of the immunology experts, rather than on Dr. Yeager's cardiology opinion. (*Id*. at 3-5.) Petitioner was cautioned that, to that point, Dr. Gershwin's opinion appeared to rest on a single paragraph of *ipse dixit*. (*Id*. at 5.)

Petitioner subsequently filed a supplemental report by Dr. Gershwin (ECF No. 48-49; Exs. 24-28) and respondent filed a responsive report by Dr. MacGinnitie (ECF No. 51; Ex. F). Thereafter, a follow up scheduling order cautioned that Dr. Gershwin's report did not appear to fully respond to the prior Rule 5 Order and petitioner was provided an opportunity to submit a further report. (ECF No. 52.) Petitioner filed a supplemental report by Dr. Gershwin in December of 2020. (ECF No. 59-60; Exs. 29-35.) Respondent responded with a further report by Dr. MacGinnitie in April of 2021. (ECF No. 68; Ex. G.)

[5] Specifically, it was noted that Special Master Millman's order appeared to be preliminary in that she found only that petitioner's argument was persuasive "at this juncture," that in any event a special master is not bound by the prior special master's ruling, and that respondent had continued to file evidence on this point following that order. (ECF No. 45, p. 2.) And, as noted above, respondent continued to raise the issue in his subsequently filed Rule 4 Report. (ECF No. 37, n. 6.) Thus, even following Special Master Millman's ruling, the question of whether petitioner met the severity requirement would need to be addressed in the ultimate decision resolving entitlement. In that regard, petitioner's expert had not directly responded to respondent's expert's contentions on this point and petitioner was encouraged to have him do so. (ECF No. 45, p. 2.)

In a status report of June 23, 2021, petitioner then requested an opportunity to retain a cardiology expert. (ECF No. 71.) Petitioner subsequently filed seven motions for extensions of time, all of which were granted.[6] (ECF Nos. 72-77, 79.) However, on September 21, 2022, noting petitioner's prolonged delay in presenting any expert cardiology opinion, the undersigned issued an order advising that the Federal Circuit's decision in *Wright v. Secretary of Health & Human Services*, 22 F.4th 999 (Fed. Cir. 2022), called petitioner's satisfaction of the statutory severity requirement further into question. (ECF No. 80.) The parties were instructed to brief that issue while awaiting petitioner's outstanding cardiology report. (*Id*.) However, petitioner's counsel then advised as of January 9, 2023, that he could not continue prosecuting the case because he had lost contact with the petitioner. (ECF No. 83.)

After a follow up status conference, an Order to Show Cause why the case should not be dismissed was issued. The order explained that,

> I conclude that petitioner has had a full and fair opportunity to address the issues raised by the prior September 2019 Rule 5 Order as well as a full and fair opportunity to develop the record of this case generally. Therefore, it is appropriate to resolve this case on the existing record. To the extent petitioner has expressed an interest in securing an expert opinion in cardiology, I provided petitioner that opportunity, but she has failed to prosecute that element of her case . . . .

(ECF No. 84, pp. 2-3.) Petitioner was still not foreclosed from filing a report by a cardiologist with her show cause response, but was advised that, whether or not petitioner filed such a report,

> I will decide under the preponderant standard based on the existing record whether this case should be dismissed based on the threshold issue presented under the statutory severity requirement. Even if I conclude that the case should not be dismissed on that basis, I may still issue an entitlement determination based on the existing record pursuant to Vaccine Rule 8(d).

(*Id*. at 3.)

Subsequently, petitioner filed letters by two of D.E.'s physicians, Drs. Johnson and Hoang (Exs. 36-37) and a response to the Order to Show Cause, but no opinion by a cardiology expert.[7] (ECF Nos. 88, 91.) The two letters raised for the first time that

[6] The first motion was due to the passing a close family member of counsel. (ECF No. 72.) However, as of the second motion, counsel confirmed retention of a cardiology expert who required additional time to prepare a report. (ECF No. 73.) The remaining motions all likewise requested further time for the expert to work. (ECF Nos. 74-77, 79.)

[7] Despite having previously confirmed that an expert had been retained (ECF No. 73) and repeatedly indicating that the expert was working on a report (ECF Nos. 74-77, 79), petitioner never presented a

D.E. may have experienced sequela of his Kawasaki disease in the form of recurrent cervical adenopathy. ("Adenopathy" or "lymphadenopathy" is the medical term for a swollen lymph node. When it is inflammatory it may also be called "adenitis" or "lymphadenitis." "Cervical" adenopathy refers to adenopathy of the neck area. *See* n. 11, *infra*.) Therefore, respondent was permitted to file an expert report by Dr. Yeager responding to the letters by Drs. Johnson and Hoang, which he did. (ECF No. 93; Ex. H.[8])

Thereafter, petitioner was directed to file complete medical records by Drs. Johnson and Hoang and was also permitted to file further letters with supporting literature by these two doctors responding to Dr. Yeager's report. (ECF No. 94.) However, petitioner did not complete any filings in response to that order. Therefore, an order was issued on May 7, 2024, advising that the evidentiary record had closed. Respondent was provided an opportunity to file a written response to petitioner's show cause presentation. Respondent filed a combined response to petitioner's show cause response and motion for a ruling on the record on July 22, 2024. (ECF No. 97.) Petitioner filed a reply on August 23, 2024. (ECF No. 98.)

On October 1, 2024, a scheduling order was issued providing the parties an opportunity to additionally submit written briefs addressing the Federal Circuit decision in *Leming v. Secretary of Health & Human Services*, 98 F.4th 1107 (2024), which interpreted the statutory severity requirement relative to "inpatient hospitalization and surgical intervention." (ECF No. 99.) Petitioner filed a written brief on October 17, 2024, and respondent filed his response on the following day. (ECF Nos. 100-01.) Thereafter, each party file a reply brief. (ECF Nos. 102-03.)

This matter is now ripe for resolution as to entitlement. The parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. *See Kreizenbeck ex rel. C.J.K. v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs*., 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual History

a. Initially filed medical records

The relevant medical facts are straightforward. D.E. received his third Prevnar vaccination on February 26, 2015, at his nine-month well child visit. (Ex. 1, pp. 7-8.) Two days later, on February 28, 2015, he presented to the emergency department with a fever, eyes rolling back, an episode of convulsions, and redness on the left side of his

cardiology opinion yet also never suggested her cardiology expert had withdrawn or explained why the expert was not able to complete any report, despite having been allowed well over a year to do so.

[8] In filing Dr. Yeager's report, respondent mistakenly included docket text indicating the report was marked as Exhibit G; however, the bates stamping within the exhibit correctly identifies it as Exhibit H.

neck with a palpable lymph node. (Ex. 5, p. 4-8.) A chest x-ray was consistent with pneumonia (perihilar haziness that could be a mild infiltrate) and he had a slightly elevated white blood cell count. (*Id*. at 9.) Initially he was felt to have been having a febrile seizure brought on by an infection and he was released. (*Id*.)

However, D.E. was brought back to the emergency department hours later after another episode of eye fluttering, non-responsiveness, and vomiting. (Ex. 5, p. 41; *see also* Ex. 1, p. 35.) This time he was admitted to the hospital and remained an inpatient until March 9, 2015. (Ex. 1, pp. 35, 40.) D.E.'s mother reported that he had not been having any upper respiratory symptoms and a respiratory virus panel was negative. (*Id*. at 35.) During hospitalization, D.E. underwent a bedside lumbar puncture under local anesthetic to rule out meningitis. (Ex. 4, p. 54.) After a normal EEG, neurology did not think D.E. was experiencing seizures. (Ex. 1, p. 41.) Ultimately, D.E. was diagnosed with atypical or incomplete Kawasaki disease[9] and he was treated with high dose aspirin (for fever) and IVIG.[10] (Ex. 4, pp. 46-52, 139-40.) D.E. received IVIG on March 6, 2015. (Ex. 4, pp. 117-20, 150, 156.) He also had a course of antibiotics for lymphadenitis of the neck.[11] (Ex. 2, p. 13.) During the course of his hospitalization, D.E.'s cervical lymphadenopathy improved with antibiotic treatment and, at the time of his discharge exam, his left cervical adenopathy was observed to be "minimal." (Ex. 1, pp. 40-41.) Subsequent follow up physical exams of D.E.'s neck were "neg" and "normal." (*Id.* at 30, 33.)

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[9] Kawasaki disease is associated with vasculitis of the large coronary vessels, as well as other systemic signs, such as fever, conjunctival injection, changes of the oropharyngeal mucosa, cervical lymphadenopathy, and maculoerythematous skin eruption that becomes confluent and bright red in a glove-and-sock distribution. *Kawasaki disease*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=70488 (last visited Oct. 8, 2024). The syndrome usually affects infants and young children, and its etiology is unknown. *Id.*

[10] Intravenous immune globulin ("IVIG") treatment is used in the treatment of a wide variety of disease and works to protect against infection and suppress inflammatory and autoimmune processes. (Orange, *supra*, at Ex. A, Tab 1; Silvergleid & Ballow, *supra*, at Ex. A, Tab 2.) Among other uses, it is a treatment for Kawasaki disease. (Sundrel, *supra*, at Ex. A, Tab 4.)

[11] Cervical adenopathy is characterized as "enlarged, inflamed, and tender cervical lymph nodes, seen in certain infectious diseases of children." *Cervical lymphadenopathy*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=87515 (last visited Nov. 1, 2024). It is also a known feature of Kawasaki disease. *Kawasaki disease*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=70488 (last visited Nov. 1, 2024). As previously indicated, cervical adenopathy can be variously referred to as cervical lymphadenopathy, cervical adenitis, cervical lymphadenitis, etc. *Adenopathy*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=968 (last visited Nov. 1, 2024); *Lymphadenopathy*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=28980 (last visited Nov. 1, 2023); *Cervical lymphadenopathy*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=87515 (last visited Nov. 1, 2024); *Cervical adenitis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=54826 (last visited Nov. 1, 2024); *Cervical lymphadenitis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=87498 (last visited Nov. 1, 2024).

As of a cardiology follow up of March 26, 2015, D.E. had a normal physical exam, was noted to be symptom free, and was described as a "10 month old with history of atypical Kawasaki disease without coronary artery dilation who is doing well, 3 weeks after initial diagnosis." (Ex. 1, pp. 32-34.) Because D.E. had not had any coronary artery changes, no antiplatelet treatment or restriction from physical activity was recommended beyond 6-8 weeks and no follow up coronary angiography was necessary; however, periodic assessment for cardiovascular risk factors was recommended every five years due to a future risk of ischemic heart disease. (*Id*. at 33.)

On May 28, 2015, D.E. saw his pediatrician. (Ex. 1, pp. 2-3.) He again had a normal exam, including cardiac examination. However, the pediatrician noted that D.E. would need to wait thirteen months to receive his MMR and varicella vaccines, because he had received IVIG three months earlier. (*Id*. at 2.) The pediatrician also remarked that D.E.'s parents were hesitant about the DTaP and Hib vaccines, given that he developed Kawasaki shortly after his Prevnar vaccination. (*Id*.)

Medical records filed through June of 2016 showed no further issues pertaining to D.E.'s Kawasaki disease. There is no indication in these records that D.E. experienced any recurrence of cervical adenopathy. No medical records have been filed to show the state of D.E.'s health after June of 2016.

b. Subsequently filed physician letters

Petitioner subsequently filed a letter by Dr. Duke Johnson[12] dated August 22, 2023, which indicated that D.E. had been a patient of Dr. Johnson for "over one year," likely indicating D.E. had become a patient sometime during 2022. (Ex. 36.) Dr. Johnson indicates that when D.E. first presented to his practice, he had a cervical adenopathy even though he was afebrile and had no other signs or symptoms of infection. He had the same issue upon physical exam as of the date of the letter. Dr. Johnson indicates that this had been a persistent recurring problem for D.E. ever since his Kawasaki disease diagnosis and Dr. Johnson opines the recurrent cervical adenopathy "is a prolonged manifestation and consequence of the disease," noting that lymphadenopathy is commonly associated with Kawasaki disease and that 50-75% of children with Kawasaki disease have associated cervical adenopathy.[13]

Petitioner also filed a letter dated September 11, 2023, by pediatrician LeTrinh Hoang, D.O. (Ex. 37.) Dr. Hoang indicates that D.E. was under her care from six months of age until the family relocated at an unspecified time. She indicates that D.E. "was diagnosed at 9 months with Kawasaki's Disease following a vaccine administration

[12] Dr. Johnson's letterhead indicates that his clinic is called "Heart of Hope Health," a name that could, but does not necessarily, suggest it is a cardiology clinic. (Ex. 36.) However, Dr. Johnson does not discuss his credential or specialty and does not represent that he is a cardiologist. In subsequent briefing, petitioner instead characterized Dr. Johnson as a "family medicine specialist." (ECF No. 98, p. 4.)

[13] Dr. Johnson did not provide any citation for this specific figure.

at another office. He continued care with me thereafter. As I recall, he had cervical lymphadenopathy and lymphadenitis as a sequala of KD. He continued to have recurrent problems despite having been treated with homeopathy and osteopathy." (*Id*.)

Petitioner has not filed medical records for either Dr. Johnson or Dr. Hoang and, despite indicating she cared for D.E. as early as six months of age, Dr. Hoang's name is not mentioned in any of the medical records that have been filed.[14]

IV. Petitioner Has Not Satisfied the Statutory Severity Requirement

As explained above, petitioner must demonstrate as a threshold matter either that D.E. underwent a surgical intervention while hospitalized for his Kawasaki disease or that he suffered complications or residual effects of his injury for at least six months. Although it is undisputed that D.E.'s Kawasaki disease in itself resolved within six months of vaccination, petitioner has presented three distinct arguments in the course of litigation as to why D.E.'s injury nonetheless meets this requirement. First, petitioner argued both before Special Master Millman and in response to the undersigned's order to show cause that D.E.'s 13-month restriction from receiving a live virus vaccine due to his IVIG treatment was a residual effect of his condition. Second, she also argued in response to the show cause order that D.E. has experienced recurrent cervical adenopathy causally attributable to his prior Kawasaki disease. And, third, although Special Master Millman had rejected the argument that D.E.'s lumbar puncture during his hospitalization constituted a surgical intervention within the meaning of the Act, petitioner reintroduced that argument in supplemental briefing in light of her interpretation of the Federal Circuit's *Leming* decision.

To resolve this threshold issue, the experts' analyses of D.E.'s clinical history is addressed first before turning to the reasons why the previously assigned special master's preliminary ruling must be revisited with respect to whether D.E. experienced complications or residual effects of his condition for at least six months. Thereafter, the undersigned renders findings on each of petitioner's three arguments. For the reasons discussed below, none of the arguments advanced by petitioner preponderantly satisfies the statutory requirement.

[14] In her reply brief following the show cause order, petitioner briefly referenced "records" by Dr. Johnson and cited to an Exhibit 38. (ECF No. 98, p. 3.) Her show cause response likewise referenced both an Exhibit 38 and Exhibit 39. (ECF No. 91, pp. 11-12.) However, no such records have been filed. No Exhibit 38 or Exhibit 39 was ever filed.

a. Expert opinion regarding complications and residual effects of Kawasaki disease

i. Dr. Gershwin for petitioner[15]

Dr. Gershwin endorses D.E.'s diagnosis of Kawasaki disease. (Ex. 10, p. 1.) He explains that Kawasaki disease is a form of vasculitis that is relatively uncommon and is seen primarily in children. (*Id*. at 1-2.) Cardiac complications of Kawasaki disease can include vasculitis, coronary artery aneurysms, an increase in the thickness of the carotid intima-media, endothelial cell dysfunction, and increased arterial stiffness. Abnormalities on echo or EKG testing in a Kawasaki patient can also indicate heightened cardiovascular risk. (*Id*. at 2 (citing Katherine Y.H. Chen et al., *Kawasaki Disease and Cardiovascular Risk: A Comprehensive Review of Subclinical Vascular Changes in the Longer Term*, 105 ACTA PAEDIATRIC 752 (2016) (Ex. 17)).) However, Dr. Gershwin acknowledges that, although all Kawasaki patients are recommended to have continued monitoring, D.E.'s arteries are normal and he "does not have evidence of continuing cardiovascular compromise and/or coronary lesions." (*Id.*)

Dr. Gershwin indicates that the pathogenesis of Kawasaki disease involves an acute inflammatory response followed by a chronic inflammatory response. (Ex. 10, p. 2.) Rather than Kawasaki disease itself involving immune suppression or constituting any form of a weakened immune state, Dr. Gershwin stresses that Kawasaki disease involves an "excessive" immune response. (Ex. 29, p. 2.) However, in D.E.'s case, he explains that D.E. had a "good response" to treatment following his IVIG and that his condition went into remission within six months and remained in remission. (Ex. 10, p. 1.)

With respect to the treating physician's decision to withhold any live virus vaccines, Dr. Gershwin opines that this recommendation recognized that treatment with IVIG produces transient immunosuppression, which would "prevent [D.E.] from mounting a normal immune response to either a viral vaccine or a virus." (Ex. 24, pp. 3-4.) However, he explains that:

> After the IVIG has been eliminated from the body, this effect will disappear. Although I agree with the thoughts of [D.E.]'s treating physicians and agree that he should not have been vaccinated during the window when he was

[15] Dr. Gershwin received his medical degree from Stanford University in 1971, before going on to complete an internship and residency from Tufts-New England Medical Center. (Ex. 11, pp. 1-2.) He is board certified in internal medicine with a subspecialty in rheumatology and in allergy and clinical immunology. (*Id.* at 2.) He currently works as the Jack and Donald Chia Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology, and a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California in Davis, California. (*Id.* at 1-2.) He also works as the Director of the Allergy-Clinical Immunology Program, a Professor of Medicine (Rheumatology and Allergy), and Chief of the Division of Rheumatology/Allergy and Clinical Immunology at the University of California School of Medicine in Davis, California. (*Id.*) Dr. Gershwin has authored nearly 1,000 experimental papers, 71 books and monographs, 164 book chapters, and 224 reviews. (*Id.* at 8-125.)

> receiving IVIG. I do agree that it is not a clinically significant immune suppression and did not impact [D.E.]'s health.

(*Id*. at 3-4 (citing Laetitia Sordé et al., *Massive Immune Response Against IVIg Interferes with Response Against Other Antigens in Mice: A New Mode of Action?*, PLOS ONE, Oct. 12, 2017 (Ex. 27); Caroline E. Tacke et al., *Reduced Serological Response to Mumps, Measles, and Rubella Vaccination in Patients Treated with Intravenous Immunoglobulin for Kawasaki Disease*, 131 J. ALLERGY & CLINICAL IMMUNOLOGY 1701 (Ex. 28; Ex B, Tab 11)); *see also* Ex. 29, pp. 1-2.) However, he also stressed that "[b]oth antigen specific and antigen-nonspecific responses are inhibited by IVIG in a dose dependent manner." (Ex. 29, p. 1 (quoting W.A.C. Sewell & S. Jolles, *Immunomodulatory Action of Intravenous Immunoglobulin*, 107 IMMUNOLOGY 387 (2002) (Ex. 30)).)

ii. Dr. Stryer for respondent[16]

As an initial matter, Dr. Stryer's report first confirms that Kawasaki disease itself does not cause any compromise or suppression of the immune system. (Ex. A, p. 1.) Moreover, even if it did, there is no evidence in this case that it would have persisted. D.E.'s medical records showed that he "recovered quickly and without sequelae," with "no evidence whatsoever in the medical records of immune suppression, either clinically or on laboratory studies." (*Id*.)

Turning to the question of why D.E. was advised not to receive live-virus vaccines, Dr. Stryer explains that IVIG is obtained from donor plasma and it transmits passive antibodies from donors to the IVIG recipient. (Ex. A, pp. 1-2.) This creates temporary immune protection. Thus, she opines that the restriction is not due to a weakened immune system, but due to the fact that the vaccine would be ineffective. (*Id*. at 2 (citing Arthur J. Silvergleid & Mark Ballow, *Overview of Intravenous Immune Globulin (IVIG) Therapy*, UPTODATE (Feb. 23, 2016) (Ex. A, Tab 2)).) She states: "D.E. was advised not to receive any live-virus vaccines for one year not because his doctors were concerned that D.E. would contract an illness, but because IVIG blunts the development of an immune response to Varivax and MMR vaccines, which is the purpose of vaccination." (*Id*.) This is of particular concern with live virus vaccines, because the IVIG antibodies prevent any viral replication that is necessary for the vaccine to produce the desired immune response. (*Id*. at 2 (citing Silvergleid & Ballow, supra, at Ex. A, Tab 2; Jan E. Drutz, *Measles, Mumps, and Rubella Immunization in Infants, Children, and Adolescents*, UPTODATE (Oct. 31, 2017) (Ex. A, Tab 3)).) Literature shows that this is the reason for withholding live virus vaccines following IVIG, because these antibodies persist for up to eleven months. (*Id*. (citing Robert Sundel,

[16] Dr. Stryer is a Medical Officer with the Division of Inquiry Compensation Programs at the Department of Health and Human Services. (Ex. A, p. 1.) In that capacity, Dr. Stryer works as part of a team of medical personnel who review and evaluate petitioner for compensation filing with the program. (*Id.*) Respondent did not file a curriculum vitae for Dr. Stryer. However, this is not a critical omission because, as discussed below, Dr. Gershwin endorsed Dr. Stryer's explanation and, in any event, her opinion is redundant of Dr. MacGinnitie's opinion.

Kawasaki Disease: Initial Treatment and Prognosis, UPTODATE (Mar. 29, 2017) (Ex. A, Tab 4)).)

Dr. Stryer acknowledges that IVIG is used to treat Kawasaki disease in order to suppress the inflammatory/autoimmune response and does suppress or neutralize cytokine response. (Ex. A, p. 2.) However, she opines that IVIG does not cause immunosuppression and that immunosuppression is not a side-effect of IVIG. (*Id*. at 3.) Potential side effects of IVIG include allergic reactions, hemolysis or breakdown of red blood cells acutely, and potential transmission of blood borne pathogens. (*Id*.) Sundel et al. demonstrates that, notwithstanding the transfer of passive antibodies blunting the vaccine response, it is within the standard of care to administer live virus vaccines to Kawasaki patients when outbreaks occur, which indicates the vaccines are considered safe. (*Id*. at 2.)

Dr. Gershwin did not dispute Dr. Stryer's opinion, remarking that she "provided an excellent overview of the use of IVIG and explained why [D.E.'s] physicians did not recommend the use of live viral vaccines." (Ex. 24, p. 3.)

iii. Dr. MacGinnitie for respondent[17]

Dr. MacGinnitie likewise explains that, although live virus vaccines are contraindicated for individuals with severe immunodeficiency, Kawasaki disease does not itself cause any immunodeficiency. (Ex. B, p. 5 (citing Francisco A. Bonilla et al., *Practice Parameter for the Diagnosis and Management of Primary Immunodeficiency*, 136 J. ALLERGY & CLINICAL IMMUNOLOGY 1186 (2015) (Ex. B, Tab 6)).) Thus, this reasoning is not implicated in this case. (*Id*.) Dr. MacGinnitie echoes the same reasoning discussed in Dr. Stryer's report, namely that vaccines are withheld for vaccine efficacy, rather than any safety concern, providing still greater detail and citing the Red Book of the Committee on Infectious Disease of the American Academy of Pediatrics as authoritative regarding this point. (*Id*. at 5-6 (citing AM. ACAD. OF PEDIATRICS, RED BOOK: 2015 REPORT OF THE COMMITTEE ON INFECTIOUS DISEASE 490 (David W. Kimberlin et al. eds., 30th ed. 2015) (Ex. B, Tab 10)).) He asserts this interpretation is further confirmed by a study by Tacke et al., which showed the MMR vaccine was less effective in Kawasaki disease patients within nine months of IVIG treatment. (*Id*. at 6 (citing Tacke et al., *supra*, at Ex. B, Tab 11).) He further stresses that there is no literature available that suggests any increased risk of infection following IVIG treatment for Kawasaki disease, which would be expected if there was genuine clinical concern of immunodeficiency. (*Id*.) Dr. MacGinnitie further explained that a review paper of secondary immunodeficiency by Chinen and Shearer

[17] Dr. MacGinnitie received his Ph.D. in pathology from the University of Chicago Pritzker School of Medicine in 1996, before going on to receive his medical degree with honors from the same university in 1998. (Ex. C, p. 1.) He went on to complete a residency in pediatrics at Boston Combined Residency Program, a fellowship in allergy and immunology at Boston Children's Hospital, and a clinical fellowship in pediatrics at Harvard Medical School. (*Id.*) He currently works as an attending physician and the Clinical Director for the Division of Immunology at Boston Children's Hospital, as well as an Associate Professor of Pediatrics at Harvard Medical School. (*Id.* at 1-2.) Dr. MacGinnitie has authored 35 peer-reviewed articles and 3 reviews, chapters, monographs, and editorials. (*Id.* at 11-15.)

identified corticosteroids, calcineurin inhibitors, and cytotoxic agents, but not IVIG, as being immunosuppressive medications. (Ex. F, p. 2 (citing Javier Chinen & William T. Shearer, *Secondary Immunodeficiencies, Including HIV Infection*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY S195 (2010) (Ex. F, Tab 2)).) He also stresses that there are clinical indicators of immunosuppression, such as increased incidences of infection and increased or unusual complications to infections, and D.E. did not display these indicators. (*Id*. at 1-2.) Dr. MacGinnitie also repeated his opinion regarding the lack of immune suppression in his final report. (Ex. G, pp. 3-4.)

iv. Dr. Yeager for respondent[18]

In his first report, Dr. Yeager discussed that D.E.'s Kawasaki disease resolved within six weeks and that he did not have any cardiovascular complications. As did Drs. Strayer and MacGinnitie, he further opined that Kawasaki disease would not have compromised or weakened his immune system. (Ex. D.) In his second report, Dr. Yeager addressed the contention that D.E. suffered chronic, recurrent cervical adenopathy resulting from his Kawasaki disease. (Ex. H.) He explains that while cervical adenopathy is a common feature of the acute manifestations of Kawasaki disease, there is no basis for concluding that occurrence of adenopathy years later would be a logical consequence of the Kawasaki disease. (*Id.* at 2.) He stresses that the adenopathy seen in Kawasaki disease generally resolves within days to weeks, along with the other symptoms of Kawasaki disease, and that benign adenopathy of childhood is an otherwise known condition. (*Id.* at 2-3.) Cervical lymphadenopathy is "extremely common" in normal, healthy children. (*Id*. at 4.) Dr. Yeager asserts there is no medical literature available to support the contention that chronic lymphadenopathy can be a long-term consequence of Kawasaki disease. (*Id*. at 3-4.) Instead, long-term consequences of Kawasaki disease typically result from complications of arteritis and therefore affect the arteries. (*Id*. at 4.)

b. Analysis of the statutory severity requirement

i. Special Master Millman's prior order

In her show cause response, petitioner stressed the fact of Special Master Millman's prior ruling as to the severity requirement, though she acknowledged it is not necessarily binding. (ECF No. 91, p. 11.) Special Master Millman had concluded that D.E.'s lumbar puncture did not constitute a surgery for purposes of the statutory severity

[18] Dr. Yeager received his medical degree from the University of Virginia in 1975, before going on to complete an internship in pediatrics at Georgetown University Hospital in 1976 and a residency in pediatrics at Medical Center Hospital of Vermont in 1980. (Ex. E, p. 1.) He is board certified in pediatrics and pediatric cardiology, and he maintains an active medical license in New Hampshire, Vermont, Massachusetts, and West Virginia. (*Id.* at 1-2.) He is the division chief of pediatric cardiology and a professor of pediatrics at the University of Vermont School of Medicine. (*Id.* at 2.) He also holds an appointment in pediatrics at Dartmouth Medical School and Dartmouth Hitchcock Medical Center. (Ex. D, p. 1.) For over 30 years, Dr. Yeager has been involved in teaching, clinical research, and the practice of pediatric cardiology. (*Id.*) He has authored 29 peer-reviewed journal articles; 22 letters, abstracts, and scientific presentations; and 7 book chapters. (Ex. E, pp. 5-10.)

requirement but found that petitioner had suffered residual effects of his vaccine injury because he "remained in a vulnerable state without symptoms or treatment." (ECF No. 24, pp. 1-2 (citing *H.S. v. Sec'y of Health & Human Servs*., No. 14-1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015)).)

Generally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred. *See McGowan v. Sec'y of Health & Human Servs.*, 31 Fed. Cl. 734, 737-38 (1994). In most cases, however, a judicial officer, such as a special master, departs from previously decided issues only in the event of "new evidence, supervening law, or a clearly erroneous decision." *Id.* at 737; *see also Sullivan v. Sec'y of Health & Human Servs.*, No. 10-398V, 2015 WL 1404957, at *20 n.36 (Fed. Cl. Spec. Mstr. Feb. 13, 2015). In this case, all three of these factors favor revisiting Special Master Millman's order with respect to whether there has been a showing of at least six months of residual effects of D.E.'s injury.[19]

First, Special Master Millman's order was issued without the benefit of the Federal Circuit's analysis in *Wright v. Secretary of Health and Human Services*, 22 F.4th 999 (Jan. 5, 2022). In *Wright*, the Federal Circuit stressed that residual effects of a vaccine-related injury must be "suffer[ed]," meaning the residual effect must be "painful or otherwise detrimental." 22 F.4th at 1007. This guidance from the Circuit is inconsistent with the prior order's framing of the issue as requiring only a potential vulnerability to subsequent harm, even in the absence of either treatment or somatic effects. For example, in *Wright*, ongoing testing for ITP was not a residual effect in a child in the absence of lingering somatic effects because it was relatively non-invasive.[20] *Id*.

Second, and relatedly, the *Wright* decision reveals that Special Master Millman's ruling was insufficient to resolve the issue. The prior ruling relied primarily on citation to a prior case, *H.S*., in which a child was found to have suffered six months of residual effects of a skull fracture because, despite being asymptomatic, his treating physicians restricted him from physical activity for greater than six months. *H.S*., 2015 WL 1588366, at *3. Based on *H.S*., Special Master Millman indicated that a treating physician's mere "belief" that a petitioner remained in a vulnerable state is sufficient to satisfy the severity requirement and she therefore did not seek to resolve the competing evidence presented by the parties with respect to whether D.E.'s restriction from

[19] As explained in the procedural history above, petitioner was provided notice that the undersigned intended to revisit Special Master Millman's ruling following the reassignment of this case, a full and fair opportunity to continue to develop the record on this point, and prompting to brief the significance of the Federal Circuit's subsequent *Wright* decision. *See Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 65-66 (2010) (indicating that a special master must "provide adequate notice to the parties of evidentiary issues and matters" to be decided).

[20] It is also worth noting that the *Wright* holding would also clearly prevent petitioner from advancing any argument that D.E.'s cardiac monitoring alone satisfied the severity requirement. Petitioner did not advance any such argument in her show cause response (*see* ECF Nos. 91, 98), but did present such an argument in front of Special Master Millman (ECF No. 17, p. 2). The fact of this argument was referenced in Special Master Millman's ruling, but it is not clear whether it was a factor in her conclusion. (ECF No. 24, p. 2.)

receiving a live virus vaccine implicated a weakened immune state as petitioner had argued. (ECF No. 24, p. 2.)

Importantly, however, what the *H.S*. special master had concluded was that the restriction from physical activity was evidence that, in the treating physician's medical judgment, the skull fracture itself would not have been fully healed by the point at which it became outwardly asymptomatic. *H.S*., 2015 WL 1588366, at *3. The Federal Circuit in *Wright* later explained that *H.S*. stands for the proposition that the restriction from physical activity constituted a course of treatment *for an ongoing condition*, stressing that in a longer course of treatment the treatment remains necessary to control the lingering condition. 22 F.4th at 1007. Thus, it was not the mere fact of the restriction from physical activity, but what that restriction evidenced regarding the child's physical condition, that supported the conclusion reached in *H.S*. Therefore, *H.S*. should not have caused Special Master Millman to sidestep the core dispute presented by the parties as to the purpose of D.E.'s restriction from live virus vaccines in this case. *Accord Felix v. Sec'y of Health & Human Servs*., 172 Fed. Cl. 626, 633-34 (2024) (observing in a case of ITP that a post-IVIG restriction from live virus vaccines was to ensure the efficacy of future vaccines and therefore did not represent any long-lasting effect of acute ITP, a likelihood of recurrence, or a somatic change in any related condition); *see also Leming v. Sec'y of Health & Human Servs*., No. 18-232V, 2022 WL 3371016, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2022) (indicating that withholding vaccines would at most represent concern regarding a risk of future recurrence, which does not constitute a residual effect under the statute), *mot. for rev. den'd*, 161 Fed. Cl. 744 (2022), *rev'd on other grounds*, 98 F.4th 1107 (Fed. Cir. 2024).

Third, Special Master Millman herself characterized her ruling as tentative, explaining that petitioner was persuasive only "at this juncture" and additional expert opinion was subsequently filed that has direct bearing on the reason for D.E.'s restriction from receiving live virus vaccines. Of particular note, subsequent to Special Master Millman's ruling, petitioner's own expert, Dr. Gershwin, agreed with Dr. Stryer's explanation of the restriction from live virus vaccines and conceded that the alleged immune suppression underlying petitioner's argument was "not a clinically significant immune suppression and did not impact [D.E.]'s health." (Ex. 24, pp. 3-4.) This bears directly on the special master's acceptance of the premise that D.E. was in a "vulnerable state." Thus, new evidence also supports revisiting the prior ruling.

ii. Residual effects or complications lasting at least six months

1. Immune suppression

The evidence clearly preponderates in favor of a finding that D.E.'s Kawasaki disease did not in itself result in a compromised or weakened immune system. Respondent's experts have affirmatively opined that it would not, and petitioner's expert has not suggested otherwise. The treating cardiologist's decision to withhold live virus vaccines, the sole evidence from the medical records relied upon by petitioner with respect to any potential immune suppression, is not inconsistent with this finding. The

cardiologist specifically stated that the vaccines were being withheld due to D.E.'s prior treatment with IVIG rather than due to the Kawasaki disease itself. (Ex. 1, p. 3.)

However, the parties disagree as to whether IVIG is immune suppressive and as to whether that would explain the treating cardiologist's concern regarding the administration of live virus vaccines. Respondent's experts are persuasive in explaining that withholding live virus vaccines is the standard of care for post-IVIG Kawasaki patients and that the reason for this relates to the efficacy of the vaccines, rather than any safety concern relative to an immunosuppressive effect of IVIG. Indeed, Dr. Gershwin confirmed that he agreed with Dr. Stryer's explanation. (Ex. 24, p. 3). Therefore, petitioner has no basis for speculating that the treating cardiologist's notation withholding live virus vaccines reflects any concern other than this established standard of care. There is no evidence that the treating physician's decision to temporarily withhold live virus vaccines reflects an opinion that D.E. was in any kind of vulnerable state.

Although petitioner filed literature indicating that IVIG likely has an immune modulating effect in the context of Kawasaki disease, this same literature explains that the mechanism underlying its effectiveness as a treatment remains unclear. (Burns & Franco, *supra*, at Ex. 7, p. 1.) Importantly, Dr. Gershwin indicates that the pathophysiology of Kawasaki disease involves an "excessive" immune response. (Ex. 29, p. 2.) Consistent with Dr. Styer's and Dr. MacGinnitie's opinions, nothing in the literature filed in this case suggests that immune modulation capable of counteracting an aberrant or excessive immune response would also have an overall suppressive effect. Even if one accepted that IVIG could result in some degree of temporary immune suppression as Dr. Gershwin suggested, Dr. Gershwin himself characterizes this as not a clinically significant immune suppression and confirmed that in his view it did not impact D.E.'s health. (Ex. 24, pp. 3-4.) Thus, Dr. MacGinnitie is persuasive in further observing that D.E. did not display any indicators of immune suppression or deficiency. (Ex. F, pp. 2-3.)

Additionally, to the extent Dr. Gershwin asserted some theoretical immune suppression, he further circumscribed his opinion by indicating that this raises an issue only "during the window when he was receiving IVIG" (Ex. 24, p. 3); however, it is not entirely clear what this means. D.E. received only a single IVIG treatment on March 6, 2015, which is consistent with the standard of care reflected in the literature petitioner filed. (Newburger et al., *supra*, at Ex. 9, p. 13 (indicating Kawasaki patients should be treated with 2 g/kg of IVIG in a single infusion); Burns & Franco, *supra*, at Ex. 7, p. 5 (noting that the majority of patients respond to a single dose of IVIG).) Dr. MacGinnitie has explained that it is the presence of donor antibodies, not any immune suppressive effect, that persists for up to about a year after treatment. (Ex. B, pp. 5-6.)

Finally, petitioner also implicitly argued that, even if the reason for withholding vaccines was related to vaccine efficacy, rather than safety, this would still represent some form of immune dysfunction, given that D.E. would be unable to appropriately process a live virus vaccine with a "normal" immune response. (ECF No. 17, pp. 2-3;

Ex. 24, p. 3.) This is not persuasive, however, because respondent's experts have persuasively established that the vaccine is rendered ineffective simply because the presence of extra donor antibodies interferes with the vaccine's ability to interact with the host's own immune cells, not because the host's immune response is in any weakened, compromised or dysregulated state. Moreover, given that Dr. Gershwin specifically confirmed that any proposed immune dysfunction would not have been clinically significant and did not impact D.E.'s health (Ex. 24, pp. 3-4), this argument is also not compatible with the Federal Circuit's decision in *Wright*. As noted above, the Federal Circuit explained that "Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." 22 F.4th at 1006. In that case, the Circuit stressed that "[o]ne does not naturally 'suffer' minimally invasive monitoring or diagnostic testing, particularly when the underlying injury was found to have resolved." *Id*. Here, it is difficult to see how temporarily deferring vaccination for maximal efficacy is "naturally suffered" to any greater degree than undergoing minimally invasive testing. *Accord Felix*, 172 Fed Cl. at 633-34.

Accordingly, there is not preponderant evidence that D.E. suffered six or more months of a suppressed, weakened, compromised, or otherwise dysfunctional, immune system following vaccination. And there is not otherwise preponderant evidence that D.E. remained in a "vulnerable state" for six or more months following vaccination.

2. Cervical adenopathy

Petitioner also more recently filed letters by Drs. Hoang and Johnson that form the primary basis for petitioner's argument within her show cause response as to why D.E.'s condition satisfied the severity requirement. (ECF No. 98, p. 3.) Drs. Hoang and Johnson represent that D.E. has experienced persistent recurrent cervical adenopathy that they attribute to his prior Kawasaki disease. (Exs. 36-37.) In order for D.E.'s recurrent adenopathy to be a complication or residual effect of his alleged vaccine-related injury, petitioner must preponderantly demonstrate that D.E.'s Kawasaki disease is a substantial contributing factor and a but for cause of the condition. *Wright*, 22 F.4th at 1005. There are two significant barriers to this showing: First, petitioner has not preponderantly substantiated the alleged recurrence. Second, even if D.E. did suffer recurrent lymphadenopathy, petitioner has not preponderantly established that it can be causally connected to his prior Kawasaki disease.

While D.E. did have a swollen cervical lymph node as part of the presentation of his Kawasaki disease, the contemporaneous medical records document that his lymphadenopathy resolved with antibiotic treatment. (Ex. 1, pp. 40-41.) Following his hospitalization, the medical records confirm as of a March 26, 2015 follow up, that his lymphadenopathy had resolved. (Ex. 1, p. 30 (physical exam of the neck noting "neg" and "normal").) None of the medical records filed in this case, which span the year following the resolution of D.E.'s Kawasaki disease and up to June of 2016, indicate that any recurrence of lymphadenopathy occurred. And, as noted in the factual summary above, no medical records have been filed for the period from June of 2016 to the

present. Thus, no medical record evidence filed in this case supports that any recurrence of lymphadenopathy occurred.

Even accepting Dr. Johnson's letter as some evidence of a subsequent recurrent lymphadenopathy, Dr. Johnson first observed D.E. having a lymphadenopathy in 2022, about seven years after D.E.'s Kawasaki disease had resolved. (Ex. 36.) Consistent with the available medical records, Dr. Hoang's letter states that D.E. had lymphadenopathy associated with his initial presentation of Kawasaki disease; however, she does not explain the "recurrent problems" she states that she subsequently observed. (Ex. 37.) Overall, despite being authored by treating physicians, the letters by Drs. Johnson and Hoang are remote to D.E.'s Kawasaki disease and insufficient to establish the timing or details of any subsequent recurrence(s) of cervical adenopathy or of D.E.'s clinical course, generally. The letters themselves are short on detail, and petitioner has not filed any medical records from either physician. Neither Dr. Johnson nor Dr. Hoang discusses when D.E. first started experiencing recurrence of this condition.

Dr. Johnson notes that D.E.'s Kawasaki disease included a lymphadenopathy and that cervical adenopathy is seen in 50-75% of children with Kawasaki disease. (Ex. 36.) Dr. Yeager explains, however, that although adenopathy can be a feature of the acute phase of Kawasaki disease, there is no medical literature available to support the contention that chronic lymphadenopathy can be a long-term consequence of Kawasaki disease. (Ex. H, pp. 3-4.) Long term consequences of Kawasaki disease are understood to relate to complications from arterial damage, and cervical lymphadenopathy is otherwise "extremely common" in childhood. (*Id*. at 4.) In that regard, D.E.'s medical records confirm within his cardiology follow ups that he had no arterial complications. (Ex. 6.) I find Dr. Yeager more persuasive on these points, especially given his credentials. Petitioner has not filed any information regarding the credentials or clinical experience of either Dr. Johnson or Dr. Huang with respect to treating or diagnosing Kawasaki disease and its complications, and Dr. Yeager contends this would not be within the ordinary experience of a pediatrician or family medicine practitioner. (Ex. H, p. 2.) Especially in light of Dr. Yeager's explanation of the conditions at issue and the commonness of lymphadenopathy in childhood, Drs. Johnson and Huang have not substantiated that cervical adenopathy remote to resolution of D.E.'s Kawasaki disease can be causally related to that condition.

Accordingly, there is not preponderant support for the contention that D.E. suffered sequela of Kawasaki disease in the form of recurrent cervical adenopathy.

iii. Inpatient hospitalization and surgical intervention

The Federal Circuit has recently addressed the meaning of "inpatient hospitalization and surgical intervention." *Leming v. Sec'y of Health & Human Servs*., 98 F.4th 1107 (Fed. Cir. 2024). In *Leming,* the Circuit explained that

> any surgical procedure – i.e., a surgical act or measure for diagnostic or therapeutic purposes taken to prevent harm of a patient or to improve the health of a patient – required to be conducted as a result of the vaccine injury qualifies, so long as the vaccine recipient is also hospitalized as an inpatient.

Id. at 1112-13. Petitioner argues that, as a result of the Federal Circuit's analysis in *Leming*, the prior caselaw addressing the meaning of the term surgery is no longer good law, effectively requiring reversal of this aspect of Special Master Millman's prior finding as to the severity requirement. (ECF No. 102.) However, this is not persuasive.

There is no question that D.E.'s lumbar puncture was the result of his allegedly vaccine-caused injury and that it was performed at a time when he was an inpatient. Under *Leming*, the specific diagnostic purpose for D.E.'s lumbar puncture is immaterial. However, this does not resolve whether it was surgical. Although the Federal Circuit's *Leming* decision for the first time clarified that the distinction between therapeutic and diagnostic procedures is not a consideration under the statutory language, it did not otherwise call into question prior decisions that have considered what constitutes a surgery, leaving unaddressed the question of what factors or circumstances would allow for the conclusion that a given act or measure "is of the surgical variety." 98 F.4th at 1111.

A procedure performed by needle puncture can be surgical, but is not necessarily so. *See Soto Galvan v. Sec'y of Health & Human Servs.*, 151 Fed. Cl. 789, 795-97 (2021); *see also Stavridis v. Sec'y of Health & Human Servs.*, No. 07-261V, 2009 WL 3837479, at *4-6 (Fed. Cl. Spec. Mstr. Oct. 29, 2009) (finding intravenous steroids and blood transfusions are not surgical); *Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *12-13 (Fed. Cl. Spec. Mstr. Jan. 16, 2014) (concluding that IVIG is not surgical). Thus, special masters have typically examined in each instance whether a needle-based procedure was considered by the treating hospital to have been a surgical procedure. This has involved consideration of a variety of factors such as whether the procedure was performed under general anesthesia and whether surgical protocols, such as written consent and post-operative recovery, were utilized. *Compare Leming*, 98 F.4th at 1113 (finding bone marrow aspiration and biopsy under general anesthesia is surgical), *and Ivanchuk v. Sec'y of Health & Human Servs.*, No. 15-357V, 2015 WL 6157016, at *3 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) (same), *with Soto Galvan*, 151 Fed. Cl. at 797 (bedside arthrocentesis of the knee is not surgical), *and Spooner*, 2014 WL 504728, at *12-13 (finding IVIG is a nursing function, not a surgery, and lumbar puncture is surgical only if performed in operating room and with general anesthesia). Petitioner characterizes this as "attempts to develop a bright line rule, like the use of general anesthesia" (ECF NO. 102, p. 2), but this is not so. Each of these prior decisions examined several factors that were significant to the question of whether the treating hospital viewed the procedure at issue as surgical.

In this case, D.E.'s lumbar puncture was performed with only local anesthetic. It appears to have been performed bedside, rather than in a surgical suite, and was

performed by a pediatric resident, not a surgeon. (Ex. 4, pp. 54-55.) Although informed consent was obtained, it appears not to have been specifically couched as a surgical consent,[21] and there was no post operative recovery after the procedure. (*Id*. at 11-14, 54-55.) Thus, D.E.'s medical records lack evidence that his own lumbar puncture was considered by the treating hospital to have constituted a surgery.

Nonetheless, petitioner argues that D.E.'s lumbar puncture was a surgical intervention because it is comparable to the bone marrow biopsy performed in *Leming*. Specifically, petitioner argues that "[b]oth the bone marrow biopsy in *Leming* and the lumbar puncture in [D.E.]'s case would be outpatient procedures but for the severity of the disease presentation in both cases." (ECF No., 100, p. 5.) However, this reasoning is contrary to prior decisions such as *Spooner*, which have explained that a given procedure may be surgical in some instances but not others. *Spooner*, 2014 WL 504728, at *12 (finding lumbar puncture is surgical only when performed in an operating room under general anesthesia). Petitioner argues that the *Spooner* case itself stands for the proposition that a lumbar puncture is a surgical intervention. (ECF No. 102, p. 2 (citing 2014 WL 504728, at *10).) However, consistent with *Leming*, what *Spooner* held was that "a lumbar puncture, when performed in an operating room with the use of general anesthesia, constitutes a 'surgery' under the Act." 2014 WL 504728, at *12. The *Spooner* special master explained that, while lumber puncture can also be performed in the emergency department by a non-surgeon, in that case "[t]he hospital records indicate that the use of general anesthesia changed the classification of the procedure to a 'Surgical Procedure.'" *Id*. Moreover, the *Leming* special master concluded that A.L.'s own procedure was surgical specifically because it was performed by a physician under general anesthesia, with consent and checklist procedures for a surgery, and post-surgical monitoring.[22] 2019 WL 5290838, at *6 (Fed. Cl. Spec. Mstr.

[21] Specifically, the title of the form is "Verification of Consent and Authorization for Surgery, Obstetrical, Special Diagnostic, or Therapeutic Procedures." (Ex. 4, pp. 11.) The pre-printed text of the form consistently references "operation(s) or procedure(s)" and "lumbar puncture" is written in as the "operation(s) or procedure(s)" at issue without any additional characterization. (*Id*.) Thus, while this appears to be the same consent form that would be used for a surgical procedure (*i.e*. operation), it is clear on its face that it is not used exclusively for surgical consent. The document includes a physician signature to confirm that the risks and benefits of the proposed care have been disclosed to the patient, but does not explain what the substance of that conversation would have entailed. (*Id*. at 14.) Notably, based on the special master's description in *Leming*, it does appear that the consent form in this case may in itself be comparable to the consent form in *Leming*. 2019 WL 5290838, at n. 7. However, because the form is broadly couched, the differing context is important. For example, the *Leming* special master specifically considered the consent form in combination with a pre-operative checklist whereas no such document exists in this case.

[22] Petitioner contends that "In *Leming*, the procedure was a bone marrow aspiration and biopsy. The published decisions in *Leming* do not reveal that this procedure was done under general anesthesia." (ECF No. 102, p. 1.) However, this is not correct. The *Leming* special master held as follows:

> In this case, the undersigned finds preponderant evidence that A.L. underwent a surgical procedure. In order to perform the bone marrow aspiration and biopsy, A.L. was placed under general anesthesia and the procedure was performed by a physician. A preoperative checklist was completed. A.L.'s mother signed a consent for a surgical procedure. A.L. was monitored by the Post Anesthesia Care Unit ("PACU") following the procedure.

Jul. 12, 2019), *mot. for rev. granted*, 154 Fed. Cl. 325, *rev'd*, 98 F.4th 1107 (Fed. Cir. 2024). Even if these precautions are not absolutely required in all instances, these factors still distinguish the bone marrow aspiration and biopsy *as performed* in *Leming* from the lumbar puncture *as performed* in this case. *Accord Galvan*, 151 Fed. Cl. at 795-97; *Spooner*, 2014 WL 504728, at *11-13.

Accordingly, there is not preponderant evidence that D.E.'s lumbar puncture constituted a surgery. The lumbar puncture therefore does not satisfy the statutory severity requirement despite having been performed while D.E. was hospitalized.

V. Petitioner Has Not Demonstrated Causation-in-Fact

Because D.E.'s injury does not meet the Vaccine Act's statutory severity requirement, this case must necessarily be dismissed regardless of whether D.E.'s Prevnar vaccination can be implicated as a cause of his Kawasaki disease. However, in the interest of completeness, it is also worth briefly explaining why petitioner has also not demonstrated that D.E.'s Kawasaki disease was vaccine caused.

a. Expert opinions regarding causation

i. Dr. Gershwin for petitioner

Dr. Gershwin describes Kawasaki disease as being of "enigmatic" etiology, though he opines it is likely as an autoimmune condition that develops as a result of genetic and environmental factors. (Ex. 10, p. 2 (citing Antonio Greco et al., *Kawasaki Disease: An Evolving Paradigm*, 14 AUTOIMMUNITY REVS. 703 (2015) (Ex. 16)).) However, he acknowledges that no defined autoantigen has been identified for the condition. (*Id.*) Rather, he suggests that it "can be considered an immunological storm consisting of pro-inflammatory cytokines produced as a result of an antigenic challenge," which he opines can include the Prevnar 13 vaccine. (*Id.*) He acknowledges that a causal connection between Kawasaki disease and vaccination cannot be established epidemiologically. (*Id.*) In fact, he notes that some studies have found that vaccination is associated with a decrease in incidences of Kawasaki disease, though he raises limitations of the available epidemiology. (*Id.* (citing Joseph Y. Abrams et al., *Childhood Vaccines and Kawasaki Disease, Vaccine Safety Datalink*, 33 VACCINE 382 (2015) (Ex. 12; Ex. B, Tab 3; Ex. D, Tab 6)).)

Dr. Gershwin provides commentary on six specific pieces of literature submitted by respondent's experts that were intended to refute a causal relationship between vaccination and Kawasaki disease. (Ex. 24, pp. 1-3.) Dr. Gershwin agrees that several of these papers do reflect that the cause(s) of Kawasaki disease remain enigmatic, but stresses that even without evidencing a causal relationship with vaccination, none of the six papers is incompatible with vaccine causation. (*Id*.) For two of the papers – Center et al. and Tseng et al. – Dr. Gershwin opines that they did detect a signal of vaccine causation based on increased incidences of Kawasaki disease following vaccination,

2019 WL 5290838, at *6 (internal citations and footnote omitted).

albeit one that did not reach statistical significance. (*Id*. at 2-3 (discussing Kimberly J. Center et al., *Lack of Association of Kawasaki Disease After Immunization in a Cohort of Infants Followed for Multiple Autoimmune Diagnoses in a Large, Phase-4 Observational Database Safety Study of 7-Valent Pneumococcal Conjugate Vaccine*, 28 PEDIATRIC INFECTIOUS DISEASE J. 438 (2009) (Ex. D, Tab 10); Jung Fu Tseng et al., *Postlicensure Surveillance for Pre-Specified Adverse Events Following the 13-Valent Pneumococcal Conjugate Vaccine in Children*, 31 VACCINE 2578 (2013) (Ex. D, Tab 12)).) Dr. Gershwin stresses the rareness of Kawasaki disease and asserts that seasonal variation in incidences of the condition underscores that it has a component of environmental stimulation. (*Id*. (citing Ritei Uehara & Ermias D. Belay, *Epidemiology of Kawasaki Disease in Asia, Europe, and the United States*, 22 J. EPIDEMIOLOGY 79 (2012) (Ex. 25); Jane C. Burns et al., *Seasonality of Kawasaki Disease: A Global Perspective*, 8 PLOS ONE e74529 (2013) (Ex. 26)).)

Dr. Gershwin acknowledges that infection is the most likely etiology for Kawasaki disease. (Ex. 29, p. 2.) He indicates that it is a "central feature" of Kawasaki disease, that it activates the immune system, and that the acute phase involves both the innate and adaptive immune responses. (*Id*. (quoting Stephanie Menikou et al., *Kawasaki Disease: The Role of Immune Complexes Revisited*, FRONTIERS IMMUNOLOGY, June 12, 2019, at 1 (Ex. 31)).) Dr. Gershwin explains that "[t]he mechanism and link between infection and Kawasaki's disease remains enigmatic, but is likely due to infection-induced uncontrolled activation of the immune system, which leads to the classic inflammatory pathology of Kawasaki's disease." (*Id*.) Dr. Gershwin posits that, because vaccines likewise induce an immune response, the host response can become excessive based on the host's genetics, regardless of whether it follows infection or vaccination. (*Id*. (citing Caroline Hervé et al., *The How's and What's of Vaccine Reactogenicity*, NPJ VACCINES, Sept. 24, 2019, at 1 (Ex. 32); Kiran Shafiq Khan & Irfan Ullah, *SARS-CoV-2 Causes Kawasaki-like Disease in Children: Cases Reported in Pakistan*, 93 J. MEDICAL VIROLOGY 20 (2021) (Ex. 33)).) He cited one study by Yung et al. that reported increased incidences of Kawasaki disease following pneumococcal vaccination, though only after the first dose. (*Id*. (citing Chee Fu Yung et al., *Kawasaki Disease Following Administration of 13-Valent Pneumococcal Conjugate Vaccine in Young Children*, SCI. REPS., Oct. 11, 2019, at 1 (Ex. 34)).) He opines this represents proof of principle that a Prevnar vaccine can initiate Kawasaki disease. (*Id*.)

Dr. Gershwin stresses that in D.E.'s case, there was no history of viral illness preceding his Kawasaki disease. (Ex. 10, p. 2.) He further indicates that onset of D.E.'s Kawasaki disease within 48 hours of vaccination is consistent with the type of acute inflammatory response he implicates in his discussion of the pathophysiology of Kawasaki disease. (*Id*. at 1.)

ii. Dr. MacGinnitie for respondent

Dr. MacGinnitie characterizes Dr. Gershwin's theory as weak and lacking any proposed mechanism of causation to explain how Kawasaki disease could be caused by a vaccination. (Ex. B, p. 3.) Moreover, he stresses that, while the cause(s) of

Kawasaki disease are unknown, there is epidemiological literature available that affirmatively evidenced that vaccinations are *not* a cause of the condition. (*Id*. at 4-5 (citing Abrams et al., *supra*, at Ex. B, Tab 3; Linny Kimly Phuong et al., *Kawasaki Disease and Immunisation: A Systemic Review*, 35 VACCINE 1770 (2017) (Ex. B, Tab 4; Ex. D, Tab 9); Wei Hua et al., *Kawasaki Disease After Vaccination: Reports of the Vaccine Adverse Event Reporting System*, 28 PEDIATRIC INFECTIOUS DISEASE J. 943 (2009) (Ex. B, Tab 5; Ex. D, Tab 7)).) Rather, Dr. MacGinnitie explains that the current consensus is that Kawasaki disease results from excessive inflammation following infection. (*Id*. at 5 (citing *S.M. Dietz et al., Dissecting Kawasaki Disease: A State-of-the-Art Review*, 176 EUR. J. PEDIATRICS 995 (2017) (Ex. B, Tab 2)).)

> There are a variety of reasons infection is suspected[,] including the fact that many children with [Kawasaki disease] have symptoms of a concomitant viral infection, the similarity of [Kawasaki disease] symptoms to infection, the spatiotemporal clustering of cases, and the fact that it occurs in young children and typically only once in a lifetime (although there are rare recurrences).

(*Id*.) Dr. MacGinnitie acknowledges Dr. Gershwin's point that a post-vaccination epidemiologic signal would be difficult to capture, given the rarity of the condition, but stresses that the Abrams study, in particular, was a large-scale study that was able to detect a decrease in incidences of Kawasaki disease following vaccination. (Ex. F, p. 2 (citing Abrams et al., *supra*, at Ex. B, Tab 3).)

Dr. MacGinnitie agrees that there is likely a causal role for environmental factors in the development of Kawasaki disease, but explains that "the seasonal pattern would argue against vaccination as a trigger as vaccinations (except for influenza) are typically given at well-child visits at specific ages, not seasonally." (Ex. F, p. 2.) Dr. MacGinnitie stresses that D.E.'s Kawasaki disease followed his third dose of the Prevnar vaccine, which he opines is inconsistent with Dr. Gershwin's theory that this particular environmental factor combined with a genetic susceptibility to cause D.E.'s Kawasaki disease. (Ex. B, p. 5.) The Yung et al. study cited by Dr. Gershwin as proof of principle at best implicates an increased risk of Kawasaki disease after only the first dose of Prevnar vaccination. (Ex. G, p. 1.) However, that study had several limitations, including its small size (the signal cited by Dr. Gershwin included only seven cases), the fact that there was no overall association detected, the failure to control for multiple comparisons (which, in Dr. MacGinnitie's opinion, means the study fails to show the finding cited by Dr. Gershwin was not a chance finding), and a risk interval for onset different than what was seen in this case. (*Id*. at 2.)

iii. Dr. Yeager for respondent

Dr. Yeager likewise asserts that the etiology for Kawasaki disease remains unknown and that vaccination is not among its suspected causes. (Ex. D, pp. 4-5 (citing Brian W. McCrindle et al., *Diagnoses, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals from the American*

Heart Association, 135 CIRCULATION e927 (2017) (Ex. D, Tab 1); Kane W. Newburger et al., *Kawasaki Disease*, 67 J. AM. COLL. CARDIOLOGY 1738 (2016) (Ex. D, Tab 2)); *see also* Ex. H, p. 1.) He suggests that temporal association is not enough to support a causal relationship, but in any event cites several studies for the proposition that no temporal relationship is established between Kawasaki disease and vaccination. (Ex. D, p. 5 (citing Abrams et al., *supra*, at Ex. D, Tab 6; Hua et al., *supra*, at Ex. D, Tab 7; Gillian C. Hall et al., *The Incidence of Kawasaki Disease After Vaccination Within the UK Pre-School National Immunisation Programme: An Observational THIN Database Study*, 25 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1331 (2016) (Ex. D, Tab 8); Phuong et al., *supra*, at Ex. D, Tab 9; Center et al., *supra*, at Ex. D, Tab 10; Dong Soo Kim et al., *Immunogenicity and Safety of 13-Valent Pneumococcal Conjugate Vaccine Given to Korean Children Receiving Routine Pediatric Vaccines*, 32 PEDIATRICS INFECTIOUS DISEASE J. 266 (2013) (Ex. D, Tab 11); Tseng et al., *supra*, at Ex. D, Tab 12).)

b. Analysis of causation-in-fact

i. *Althen* prong one

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006)). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Boatmon,* 941 F.3d 1351, 1359 (Fed. Cir. 2019) (internal citation omitted) (quoting *Knudsen*, 35 F.3d at 548-49).

Much of the expert discussion in this case is centered on epidemiology. The Federal Circuit has previously stressed that a petitioner is not obligated to present an epidemiological case supporting her claim. *Capizzano*, 440 F.3d at 1325. Nonetheless, "[n]othing in *Althen* or *Capizzano* requires the Special Master to ignore probative epidemiological evidence that undermines petitioner's theory." *D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 811 (Fed. Cir. 2018) (citing *Andreu*, 569 F.3d at 1379 for the proposition that, "[a]lthough *Althen* and *Capizzano* make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the Special Master can consider it in reaching an informed judgment as to whether a particular vaccination

likely caused a particular injury"). Here, without treating it as dispositive, the available epidemiology does carry some weight *against* petitioner's claim.

On petitioner's behalf, Dr. Gershwin acknowledges not only that petitioner's claim cannot be supported epidemiologically, but also that relevant studies have examined the proposed link between the Prevnar vaccine and Kawasaki disease and found either no association or a decreased risk of Kawasaki disease following vaccination. (Ex. 10, p. 2.) Even if accepting Dr. Gershwin's reasoning as to why a lack of epidemiologic support should be viewed as less meaningful, this still would not point to any affirmative evidence supporting petitioner's theory. Dr. Gershwin highlights some findings that he suggests show increased incidences of post-vaccination Kawasaki disease, but concedes that these results did not reach statistical significance. (Ex. 24, pp. 2-3 (citing Center et al., *supra*, at Ex. D, Tab 10; Jung Fu Tseng et al., *supra*, at Ex. D, Tab 12).) Dr. Gershwin has not substantiated that it would be reasonable to rely on such results. *See J.C. v. Sec'y of Health & Human Servs.*, No. 17-69V, 2024 WL 3412625, at *19-20 (Fed. Cl. Spec. Mstr. May 16, 2024) (criticizing Dr. Steinman's failure to explain why a study was "impressive," despite a lack of statistical significance, because statistical significance "is not simply a question of characterizing the size of an increase in the incidence rate[,] . . . . [i]t implicates whether the increase actually exists *at all* given the limitations of the available data"). Moreover, as Dr. Gershwin acknowledges, the epidemiology is notable for demonstrating seasonal fluctuations in the rate of Kawasaki disease, which is more consistent with an infectious cause, as Dr. MacGinnitie observed. (*Compare* Ex. 24, p. 2, *with* Ex. F, p. 2.)

The Yung study is the only study of record cited by Dr. Gershwin that purports to find a statistically significant link between the Prevnar vaccine and Kawasaki disease, but the finding is of limited significance for the reasons explained by Dr. MacGinnitie. In particular, the specific finding Dr. Gershwin cites was based on only seven cases and, despite finding an increased risk after a first dose based on those seven cases, the study did not find any overall increased incidences of Kawasaki disease following Prevnar vaccination. (Yung et al., *supra*, at Ex. 34.) The authors acknowledge several prior studies that found no association and themselves indicate that "[t]here is an urgent need to confirm this finding in future studies." (*Id.* at 2, 4.) Especially given Dr. MacGinnitie's methodologic criticisms, this finding by Yung et al. does not, standing alone, outweigh the overall epidemiologic picture.

Apart from attempting to overcome contradictory epidemiology, Dr. Gershwin's causal theory is otherwise limited to simply proposing that if an infection can commence the type of uncontrolled immune response that leads to Kawasaki disease, then so too can a vaccination. (Ex. 29.) However, there are meaningful differences between the immune responses to vaccination and infection. Dr. Gershwin has not substantiated his assertion that vaccination can be implicated as a precipitant of an uncontrolled immune response in the same manner as an infection. This is an especially concerning limitation to Dr. Gershwin's opinion, because the experts agree that the cause(s) of Kawasaki disease are still considered unknown and the exact causal relationship between infection and Kawasaki disease remains unclear. (*Compare* Ex. 10, p. 2, *with*

Ex. B, p. 5, *and* Ex. D, pp. 4-5.) Ultimately, Dr. Gershwin's assertion is not supported by any explanation beyond the fact that vaccines are intended to provoke immune responses. (Ex. 29, p. 2.) Special Masters have previously held that mere invocation of a vaccine's intended immune response is inadequate to support a theory of causation under *Althen* prong one. *See, e.g.*, *Vanore v. Sec'y of Health & Human Servs.*, No. 20-0870V, 2024 WL 3200287, at *18 (Fed. Cl. Spec. Mstr. May 31, 2024); *Kalajdzic ex rel. A.K. v. Sec'y of Health & Human Servs.*, No. 17-792V, 2022 WL 2678877, at *23 (Fed. Cl. Spec. Mstr. June 17, 2022), *mot. for rev. den'd*, No. 17-792V, 2024 WL 4524777 (Fed. Cl. Oct. 18, 2024), *aff'd*, No. 2023-1321, 2024 WL 3064698 (Fed. Cir. June 29, 2024); *Cordova v. Sec'y of Health & Human Servs.*, No. 17-1282V, 2021 WL 3285367, at *17 (Fed. Cl. Spec. Mstr. June 23, 2021).

For all these reasons, petitioner has not met her burden of proof under *Althen* prong one.

ii. *Althen* prongs two and three

Whereas *Althen* prong one generally speaks to the question of whether a vaccine can cause a particular injury, *Althen* prongs two and three generally speak to whether the vaccine did so in the case at hand, asking respectively whether there is a logical sequence of cause and effect and timing that would support a causal inference. *Althen*, 418 F.3d at 1278. Because I have concluded that petitioner has not demonstrated that the vaccine at issue in this case likely can cause Kawasaki disease, it is not necessary to address in detail whether it did so in this particular case. Given the outcome regarding *Althen* prong one, it necessarily follows that it likely did not. Nonetheless, it is notable that Dr. Gershwin's opinion is inadequate to support the contention that D.E.'s Prevnar vaccine did cause his Kawasaki disease.

Dr. Gershwin's opinion on specific causation is based on only two points. He opines that (1) there was no history of viral illness preceding D.E.'s Kawasaki disease, and (2) onset of D.E.'s Kawasaki disease within 48 hours of vaccination is consistent with the type of acute inflammatory response he implicates in his discussion of the pathophysiology of Kawasaki disease. (Ex. 10, pp. 1-2.) Petitioner confirms in her show cause reply that this is the full extent of her showing under *Althen* prong two. (ECF No. 98, p. 2.) Petitioner does not otherwise identify any treating physician that opined that D.E.'s own Kawasaki disease was vaccine-caused. Nor does my review of the medical records reveal any such opinion.

However, the Federal Circuit has explained that, "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149). Thus, even assuming Dr. Gershwin is persuasive with regard to both of his factual predicates, this does not preponderantly support petitioner's claim. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that

petitioner must posit a medical theory causally connecting the vaccine and injury"), *aff'd per curiam sub nom. Veryzer v. United States*, 475 F. App'x 765 (Fed. Cir. 2012); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to *Althen* prong two when respondent conceded that petitioner met *Althen* prong three).

VI. Conclusion

Although D.E. had a good recovery, petitioner had no way of knowing that when he first began experiencing symptoms and was hospitalized at only about nine months of age. I have no doubt that D.E.'s Kawasaki disease was quite frightening. Nothing in this decision is intended to minimize what D.E. and his family experienced. However, for all the reasons discussed above, petitioner has not demonstrated by preponderant evidence either that D.E.'s Kawasaki disease was vaccine caused or that, even if it were, his injury meets the other requirements for compensation in this program, namely the statutory severity requirement. Accordingly, this case is dismissed.[23]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[23] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.